

REMARKS

Reconsideration of the above-identified application in view of the foregoing arguments is respectfully requested.

Claims 63, 57, 70, 72, 75 and 79 have been amended. No new matter has been added as a result of these amendments.

Rejection of Claims 60-68 and 70-79 Under 35 U.S.C. Section 101

Claims 60-68 and 70-79 are rejected under 35 U.S.C. Section 101 as lacking a specific, substantially asserted utility or a well-established utility. Specifically, the Examiner states that the specification has not disclosed a correlation between the recited polynucleotides and the existence of breast cancer such that the skilled artisan would be able to have a real world context of use for the claimed method. According to the Examiner, a showing that a particular sequence is over represented in a particular tissue is not considered a specific and substantial utility but is instead considered a general utility that a large number of polynucleotides possess. Applicants respectfully traverse this rejection.

In the previous Office Action and in response to a utility rejection contained with the Office Action, Applicants submitted a 37 C.F.R. Section 1.132 declaration of Dr. Paula Friedman (“Declaration”). The purpose of this declaration, as correctly pointed out by the Examiner, was to establish a correlation between breast cancer and the BS106 polynucleotide. The Declaration provided data showing the results of experiments conducted on lymph node tissue from breast cancer patients and non-breast cancer patients. This data demonstrated that BS106 is expressed in breast cancer cells that have escaped the primary tumor. More specifically, BS106 was detected in 9/9 cancer lymph nodes and 1/20 normal lymph nodes.

Despite this evidence, the Examiner states that the Declaration and arguments submitted in the previous response are insufficient to overcome the rejection. Specifically, the Examiner states that the Declaration does not establish a patentable utility for BS106 polynucleotides because the utility of BS106 described in the declaration is not a utility which has been asserted in the specification. According to the Examiner, “[T]he specification has only described the use of BS106 for detecting breast tissue and breast cancer by detecting BS106 in [sic] breast tissue. The specification does not describe testing lymph nodes for the presence of breast cancer cells using a BS106 polynucleotide. The specification does not provide any teaching that BS106 was thought to be associated with metastatic breast cancer cells but instead asserts its association to breast cancer in breast tumors from breast tissue.” The Examiner then admits that “although the data does establish that BS106 could be used to detect breast cancer lymph node tissues, this is a specific and substantial utility which was not described in the specification and consequently, is not an asserted utility.”

Applicants submit that they are puzzled by the Examiner’s reasoning. It is well known in the art that most breast cancers spread through the lymph nodes. In fact, stated another way, it is well known in the art that if breast cancer is going to spread throughout the body, the majority will do so by invading the lymphatics first. The fact that BS106 can be detected in breast cancer cells that escape the primary tumor is extremely useful to clinicians in determining whether or not breast cancer has spread. These facts support that BS106 is an important marker that can be used to improve the staging of breast cancer. As discussed on page 3, lines 2-5, “[S]uch markers could be mRNA or protein markers expressed by cells originating from the primary tumor in the breast but residing in blood, bone marrow or lymph nodes and could serve as sensitive indicators for metastasis to these distal organs.”

The specification teaches that BS106 can be used for a number of different purposes. First, BS106 can be used to detect a target polynucleotide or target mRNA in a test sample (see page 5, lines 2 - page 6, line 21). The term “test sample” is defined on

page 18, lines 18-31. As discussed in this portion of the specification, a test sample is typically anything suspected of containing a target sequence. A test sample is further described as including "human and animal body fluids such as whole blood, serum, plasma, cerebrospinal fluid, sputum, bronchial washing, bronchial aspirates, urine, lymph fluids and various external secretions of the respiratory intestinal and genitourinary tracts, tears, saliva, milk, white blood cells, myelomas and the like; biological fluids such as cell culture supernatants; tissue specimens which may be fixed; cell specimens which may be fixed" (emphasis added). Second, BS106 can be used as a marker for disease such as breast cancer. Clearly, the detection of BS106 in a test sample, such as lymph fluids and lymph nodes(which is a tissue specimen) is supported by the specification.

Therefore, in view of the aforementioned arguments, Applicants submit that the above rejection should be withdrawn.

Rejection of Claims 63, 64 and 70-79 Under 35 U.S.C. Section 112, First Paragraph

Claims 63, 64 and 70-79 are rejected under 35 U.S.C. Section 112, first paragraph, as containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed had possession of the claimed invention.

Applicants have amended claims 63, 67, 70, 72, 75 and 79 to address the rejections raised by the Examiner. In view of these amendments to the claims, Applicants submit that this rejection should be withdrawn.

Rejection of Claim 67 Under 35 U.S.C. Section 112, Second Paragraph

Claim 67 is rejected under 35 U.S.C. Section 112, second paragraph as being indefinite.

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Claim 67 has been amended as suggested by the Examiner. Applicants thank the Examiner for her helpful suggestion. In view of this amendment to claim 67, Applicants submit that this rejection should be withdrawn.

Conclusion

In view of the aforementioned arguments, Applicants respectfully submit that the above-referenced application is now in a condition for allowance and Applicants respectfully request that the Examiner withdraw all outstanding objections and rejections and passes the application to allowance.



Respectfully submitted,
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MARKED UP VERSION SHOWING CHANGES MADE:

IN THE CLAIMS:

Please amend claims as follows:

63. (Amended). A recombinant expression system comprising a nucleic acid sequence that includes an open reading frame operably linked to a control sequence compatible with a desired host, wherein the nucleic acid sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, [position 14482 of] SEQ ID NO:4 and degenerate codon equivalents thereof.

67. (Twice Amended). A[n] [isolated] purified nucleic acid encoding an amino acid sequence [comprising] of SEQ ID NO:16 and fragments thereof.

70. (Amended). A method of detecting a presence of a target polynucleotide in a test sample, the method comprising the steps of:

- (a) contacting a test sample with at least one reagent polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, [position 14-482 of] SEQ ID NO:4, SEQ ID NO:5 and degenerate codon equivalents thereof; and
- (b) detecting a presence of the target polynucleotide in the test sample.

72. (Amended). A method for detecting an amplicon in a test sample taken from a patient, the method comprising the steps of:

- (a) obtaining a test sample from a patient;

- (b) performing reverse transcription with at least one primer in order to produce cDNA;
- (c) amplifying the cDNA obtained from step (b) using sense and antisense primers to obtain an amplicon;
- (d) detecting a presence of the amplicon in a test sample;

wherein the primers utilized in steps (b) and (c) are selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, [position 14482 of] SEQ ID NO:4, SEQ ID NO:5 and degenerate codon equivalents thereof.

75. (Amended). A method of detecting a target polynucleotide in a test sample taken from a patient, the method comprising the steps of:

- (a) obtaining a test sample from a patient;
- (b) contacting the test sample with at least one first oligonucleotide as a sense primer and with at least one second oligonucleotide as an anti-sense primer and amplifying to obtain a first stage reaction product;
- (c) contacting the first stage reaction product with at least one third oligonucleotide to obtain a second stage reaction product, with the proviso that the at least one third oligonucleotide is located 3' to the first and second oligonucleotides utilized in step (b) and is complementary to the first stage reaction product; and
- (d) detecting the second stage reaction product as an indication of a presence of the target polynucleotide,

wherein the oligonucleotides utilized in steps (b) and (c) are selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, [position 14482 of] SEQ ID NO:4, SEQ ID NO:5 and degenerate codon equivalents thereof.

79. (Amended). A test kit comprising:

a container containing at least one polynucleotide [encoding a mucin and] selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, [position 14-482 of] SEQ ID NO:4, SEQ ID NO:5 and degenerate codon equivalents thereof.